

BASIC.034DV1C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Potter, et al.
Appl. No. : 10/659,941
Filed : September 11, 2003
For : METHOD FOR
CONCENTRATING BETA-
GLUCAN FILM
Examiner : Henry, Michael C.
Group Art Unit : 1623

CERTIFICATE OF FAX TRANSMISSION

I hereby certify that this correspondence and all marked attachments, are being transmitted via facsimile to the USPTO centralized Fax No. (571) 273-8300 on the date shown below.

February 27, 2006

(Date)


Mallery K. de Merlie, Reg. No. 51,609DECLARATION OF RICHARD C. POTTER, Ph.D., UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Richard C. Potter, declare and state as follows:

1. I am the first named inventor on the above-captioned patent application. I presently serve as Chief Science Officer at Nurture, Inc., the assignee of the above-captioned patent application. Research initiatives at Nurture, Inc. relate to the development of viable commercial processes for manufacturing concentrated oat beta-glucan.

2. I have reviewed the above-captioned application in its entirety, including the specification and claims. I have also reviewed the contents of the file history of the above-captioned application including each of the Office Actions and all the references cited therein.

3. I received a Bachelor of Science in Chemical Engineering from Princeton University, and a Master of Science and Doctor of Philosophy in Chemical Engineering from Yale University. My *curriculum vitae* is attached as Exhibit A.

4. I have extensive experience in the field of polymer science, including commercial manufacturing processes relating to polymers. I joined Nurture, Inc. in 1988 as the Vice President of Research and Development and, since, have held the positions of Chief Operating Officer and Director and President. Since 1996, the grain-derived polysaccharide generally known as beta-glucan has been my principal area of Research and Development responsibility at Nurture, Inc. In particular, my focus has been on the development of manufacturing processes for the isolation of concentrated oat beta-glucan. My initial work with Nurture, Inc. in the isolation of concentrated oat beta-glucan involved precipitation of beta-glucan using alcohol. My later efforts focused on the development of an alcohol-free method for concentrating beta-

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glucan. As such, I have extensive personal experience with alcohol-based protocols and alcohol-free protocols for the concentration of beta-glucan.

5. Beta-glucan derived from grain, such as oats, has a mixed linkage structure [(1-3),(1-4) beta-D-glucan] which causes it to be water-soluble. Oat beta-glucan is comprised of about 30% beta-(1-3) and 70% beta-(1-4) linkages, with none of the (1-3) linkages being adjacent to one another. The polymer chain is unbranched and has a chainlike structure. Like most other polymers, beta-glucan is polydisperse, and chains of varying length (i.e., molecular weight) are always present.

6. Beta-glucan is entirely located in, and is the predominant constituent of, cell walls in the oat seed; the cell walls are particularly thick in the subaleurone layer located near the periphery of the seed. Because commercial oat bran is rich in subaleurone content, it has a higher beta-glucan content (at least 5.5%) than whole oats (ca. 2-3%). Although it is possible to concentrate beta-glucan from whole oats or oat bran by dry milling techniques, such as sieving or air classification, these methods result in products containing no more than about 25% beta-glucan. This limitation is largely a consequence of other seed constituents tightly adhering to the cell walls.

7. In order to achieve substantially higher beta-glucan concentrations, it is necessary to utilize aqueous extraction. Beta-glucan builds very high viscosity at low solution concentrations, and this constrains maximum solution concentrations to no more than about 3% w/w, which corresponds to a molasses-like consistency. Practical working solutions are on the order of 1% w/w. As such, comparatively large quantities of water must be eliminated if a solid form of concentrated beta-glucan is desired. The conventional means for effecting this is the addition of a substantial amount of an alcohol, especially ethanol or isopropanol, to the beta-glucan solution. Although beta-glucan is soluble in water, it is insoluble in alcohol, and this leads to precipitation of the beta-glucan from solution.

8. It is well-known that longer chains of an unbranched polymer are less soluble than shorter chains in any given solvent. Accordingly, when alcohol is combined with an aqueous solution of beta-glucan, the least soluble chains are preferentially precipitated (corresponding to higher molecular weight chains), the most soluble (i.e., lower molecular weight) chains remain in solution. Thus, it is clear that only a portion of the dissolved beta-glucan (corresponding to the higher molecular weight chains) will be precipitated in alcohol. As such, the beta-glucan recovered from alcohol precipitation does not exhibit the range of chain length seen in beta-glucan that has not been precipitated by alcohol.

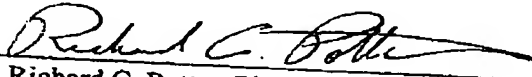
9. The partitioning of beta-glucan which arises as a result of alcohol precipitation means that its molecular weight distribution and, therefore, its chemical, physical, and biological properties will differ from beta-glucan which has not been precipitated in alcohol. The molecular weight of alcohol-precipitated beta-glucan will always be biased toward a higher range. Beta-glucan which remains in solution or is fully recovered by other means in solid form will, of course, retain the full range of polydisperse beta-glucan molecules and their associated properties. Accordingly, the concentrated beta-glucan claimed in the present application represents a full range of molecular weight, whereas the beta-glucan recovered from a process involving alcohol precipitation such as that described in Wang et al (U.S. 5,512,287) represents only a truncated range of molecular weight. The chemical, physical and biological properties of

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the beta-glucan claimed in the present application are different from the beta-glucan described in Wang et al.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By:



Richard C. Potter, Ph.D.

Date:

Feb. 27, 2006

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EXHIBIT A.***RICHARD C. POTTER, Ph.D.******117 HERITAGE DRIVE C-2
STEVENSVILLE, MONTANA 59870******TEL 406/777-4020
FAX 406/777-4021
potter@montana.com*****SUMMARY**

Accomplished in the development and commercialization of significant new product and process technologies in diverse areas. Extensive experience in all aspects of developing and commercializing a variety of household chemical, pharmaceutical/nutraceutical, and agrichemical products, including Hartz® flea collar, No-Pest Strip®, Task® and Equigard® veterinary pharmaceuticals, Shell® child-safe aerosol insecticides, Open Air® air freshener, Instead® hygiene device, as well as grain-derived OatVantage® and Nurture® nutritional and cosmetic ingredients. Experienced with both natural and synthetic polymer-based systems, including application development, formulation, process development, and testing expertise. Experienced in manufacturing and quality control issues.

Extensive management and senior management experience, primarily involving technology development and commercialization as well as operations management. Accomplished team-builder and developer. Well-rounded business background, including experience with both multinational and entrepreneurial enterprises. Knowledgeable in regulatory and patent & licensing matters.

Fifteen years with Shell Oil and seventeen years with Nurture, Inc.

MAJOR ACCOMPLISHMENTS

- Led technology development for a natural products company from startup through development stage. Established, staffed, and managed operation of all laboratory and production facilities. Validated the company's core technology and discovered numerous patentable applications of the technology in the areas of personal care, pharmaceuticals, nutrition, agrichemicals, and environmental remediation. Developed all manufacturing processes.
- Chief Operating Officer for natural products company. Oversaw plant permitting, construction, startup and operation. Established Good Manufacturing Practices program, including quality assurance program. Also responsible for R&D group, technical service group, agronomy program, and corporate administration. Responsible for regulatory and patent matters. Raised substantial capital.
- Managed development of consumer products for multinational company and administered annual budget. Oversaw programs worldwide at various laboratory

RICHARD C. POTTER, Ph.D.**PAGE 2**

facilities which led to development and commercialization of variety of household chemical products. Developed various licensing agreements.

- Member of personal staff group for president of major oil company. Participated in corporate planning and investment strategy. Developed novel discounted cash flow techniques for long-range planning subsequently adopted as company standard.
- Member of 3-man deal-making group engaged in major acquisitions and joint ventures in coal and other minerals for major oil company (\$30-300 MM range).
- Member of the research group which developed the No-Pest® Strip and Hartz® flea collar, as well as several other controlled release products involving household, pharmaceutical, and agricultural chemicals. Named group leader. Served as technical auditor for manufacturing facilities, technical liaison for patent matters, liaison to other company laboratories, and advisor for regulatory matters.
- Extensive product development experience. Trained in basic and applied polymer science, including graduate and postdoctoral research and industrial experience with two leading plastics manufacturers. Holder of numerous issued and pending U.S. and international patents. Broad experience in technology development and evaluation. Specialist in developing value-added technologies. Comprehensive patent & licensing experience.

BUSINESS HISTORY

1988-2002: NURTURE, INC., Missoula, Montana

•Nov. 1988–Sept. 1992, Vice President Research & Development. Responsible for directing and administering all technical matters, including product and process development, plant construction, patent filing and defense, university collaboration, budgeting and planning, and technical support for business development. Elected to board of governors for Montana Center of Excellence in Biotechnology (1990-93); member of board of governors for Montana Molecular Biology Center (1991-2002); Faculty Affiliate of the University of Montana (1991-2002).

•Oct. 1992–Dec. 1994, President, Chief Operating Officer, and Director (with continuing service from 1994-2002 as Director). Responsible for most operations of the company, including plant start-up and production, quality assurance, warehousing & shipping, agronomy, and research & development. Implemented Good Manufacturing Practices. Oversaw development and execution of annual operating plan and budget. Negotiated deals to finance plant and associated real estate. Worked with Chairman to raise \$9 MM investment capital. Instrumental in establishing strategic alliance with Monsanto Company. Also served on scientific advisory board of UltraFem, Ltd. and played major role in development of new feminine hygiene product.

RICHARD C. POTTER, Ph.D.**PAGE 3**

- Jan. 1995-Jan. 1996. Consulted for various companies in technology and business development, including development of formulation and delivery systems for new biopharmaceuticals and development of new environmental remediation technology. Board member of Legere Pharmaceuticals, Ltd. (1995-present).

- Feb. 1996-Jan. present. Returned as President of Nurture at request of Board to take charge of operations and assist with restructure of corporate finances, including the recruitment of new investors. Stayed on as Executive Vice President in charge of R&D and oversight of operations at request of new investors; re-engineered process technology for existing products and led development of major new product. Played key role in establishing strategic alliance with General Mills. Resigned in 2002 to pursue other opportunities but, at request of Board, have continued to provide consulting services as Chief Science Officer (2002-present).

1967-1982: SHELL OIL COMPANY

- 1967, Engineer, Plastics Technical Center (Woodbury, New Jersey). Responsible for developing various grades of olefin polymers.

- 1968-1972, Group Leader, Formulations Department, Biological Sciences Research Center (Modesto, California). Product development activities in consumer products, agrichemicals, and animal health.

- 1973-1976, R&D Manager, Consumer Products (San Ramon, California). Responsible for directing and administering all technical matters related to consumer products. Extensive interaction with marketing and manufacturing.

- 1977-1982, Various executive positions (Houston, Texas) including planning functions for president of company and acquisition activities for president of mining division. Broad exposure to senior management with emphasis on legal, tax, and investment planning.

1983-1988: Resigned to pursue personal interests in Montana, including founding and serving as president and managing editor of Pathfinder Press, Inc., a publishing company with products ranging from an award-winning weekly newspaper to recreational guides and national newsletters. Sold company in 1988 and it has continued as a successful enterprise.

EDUCATION

Princeton University	B.S.E. (Chem. E.)	1963
(Dupont Scholarship)		
Yale University	M.S. (Chem. E.)	1965
(Yale Scholarship)		
Yale University	Ph.D. (Chem. E.)	1966
(Concurrent appointment at Brookhaven National Laboratory)		

RICHARD C. POTTER, Ph.D.

PAGE 4

University of Cologne Postdoctoral 1967
(Fellow of the German Research Ministry, Sigma Xi grantee)

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